1-year clinical investigation on the On1 Concept

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45511

Source
ToetsingOnline

Brief title
On1 clinical investigation

Condition

- Other condition

Synonym
edentulism, missing teeth

Health condition

tandheelkundige behandeling

Research involving
Human

Sponsors and support

Primary sponsor: Nobel Biocare services AG
Source(s) of monetary or material Support: Nobel Biocare services AG

Intervention

Keyword: Nobel Active, On1

Outcome measures

Primary outcome

Primary Objective

The primary objective of this clinical investigation is to evaluate the change in marginal bone levels (DMBL) of the On1 Concept from prosthetic delivery up to 1 year after prosthetic delivery.

Secondary outcome

Secondary Objective

The secondary objectives of this clinical investigation are:

* To evaluate the soft tissue levels at 2 weeks after implant insertion, prosthetic delivery and 1 year after implant prosthetic delivery.

* To demonstrate the component survival and success by clinical measurement for the study period of 1 year.

* To determine the patient*s pain perception after throughout the study period of 1 year.

* To determine pre- and postoperatively the impact of the On1 Concept on the patient*s oral health related quality of life.

* To demonstrate the patient*s satisfaction, post prosthetic delivery with function and esthetics.

* To demonstrate the ease of use and the clinician*s confidence in the On1

Concept

* To record complications

Study description

Background summary

Edentulism, partial or full, is a common health issue. Treatments range from no treatment to bridges for smaller gaps and conventional dentures for total edentulism. An alternative is to place fixed implant restorations, which can be used to treat indications ranging from single tooth gaps up to full edentulism. Implants are inserted by health care professionals such as dentists, oral surgeons or oral-maxillofacial surgeons.
In conventional procedures one-piece abutments are used. First a temporary abutment is placed at the time of implant surgery. After healing period, the provisional abutment is removed and a final abutment as a base for the final restoration is placed.
With the disconnection of the provisional abutment the initial soft tissue attachment may be compromised. However, proper soft tissue adhesion to the dental restoration is important to maintain good soft tissue health and provide proper bacterial barrier.
Therefore, the On1 Concept consists a two-piece abutment with a On1 Base that is placed to the implant at time of surgery and not disconnected thereafter. A provisional abutment can be placed onto the On1-Base and easily be exchanged when the final abutment is placed. For this reasons the On1 Concept keeps the initial soft tissue attachment intact and allows for good soft tissue health and bacterial barrier.

Study objective

Primary Objective
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Secondary Objective
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of 1 year.
* To determine pre- and postoperatively the impact of the On1 Concept on the patient*s oral health related quality of life.
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* To record complications

Study design

This will be a 1-year, open, prospective, clinical multi-center investigation on the On1 Concept and NobelActive implants. A total of 68 patients in need for single tooth replacement or 3-unit restoration in the canine-, premolar- and molar area of the maxilla or mandible will be treated in four study centers and followed up to 1 year after prosthetic delivery.
The NobelActive implant(s) will be placed and the On1 Base will be screwed onto the implant. Thereafter, an On1 Healing Cap will be attached onto the On1 Base in order to protect the On1 Base connection during the healing phase. Two weeks after implant surgery, the patient will be recalled to take a digital impression with the use of an intra-oral scanner. After 10 weeks of healing the final prosthetic will be delivered and loaded (early loading protocol).
Subjects will be consecutively included provided they meet all of the inclusion criteria and none of the exclusion criteria. The follow-up period for all included subject will be 1 year calculated from final prosthetic delivery.
Overall, all patients will attend 6 follow-up visits including implant insertion. At five of these visits radiographs will be taken: implant insertion, final prosthetic delivery, 6- and 12 months follow-up visits.
Possible dropouts and withdrawals, as well as possible adverse events, will be carefully monitored during the entire investigation period.

Intervention

On1 concept NobelAcitve impant

Study burden and risks

no study specific risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The subject is at least 18 years of age (or age of consent) and has passed cessation of growth.
* Obtained informed consent from the subject.
* The patient is willing and able to comply with all study related procedures (such as exercising
oral hygiene and attending all follow-up procedures).
* The subject shall be healthy and compliant with good oral hygiene.
* Full-mouth bleeding score (FMBS) lower than 25% [10].
* Full-mouth plaque score (FMPI) lower than 20% [11].
* Suitable for implant treatment in the posterior, pre-molar and canine area in the mandible or
maxilla.
* The subject shall have a favorable and stable occlusal relationship.
* In need of one or multiple single tooth replacements or 3-unit bridges.
* Healed sites in need for implant placement (i.e. minimum of 6 weeks post extraction).
* The implant sites are free from infection and extraction remnants.
* The subject is suitable for a 1-stage surgical procedure.
* Sufficient amount of buccal and lingual keratinized mucosa.

* The subject has a sufficient amount of bone for placing NobelActive implants with a length of
at least 8 mm.
* Primary implant stability as assessed by manual hand testing.

Exclusion criteria

* The subject is not able to give her/his informed consent of participating.
* Health conditions, which do not permit the surgical (including anesthesia) or restorative procedure.
* Reason to believe that the treatment might have a negative effect on the subject*s overall situation (psychiatric problems), as noted in subject records or in subject history.
* Any disorders in the planned implant area such as previous tumors, chronic bone disease or previous irradiation in the head/neck area.
* Infections in the planned implantation site or adjacent tissue.
* Acute, untreated periodontitis in the planned implantation site or adjacent tissue.
* Any ongoing application of interfering medication (steroid therapy, bisphosphonate, etc.).
* Uncontrolled diabetes, i.e. a subject with diagnosed diabetes that has a history of neglecting
doctor*s recommendations regarding treatment, food and alcohol intake or A1c level above 8%.
* Alcohol or drug abuse as noted in subject records or in subject history.
* Smoking of >10 cigarettes/day.
* Fresh extraction sites (up to 6 weeks).
* Severe bruxism or other destructive habits.
* Pregnant or lactating women at the time of implant insertion.
* Previous bone augmentation (lateral and/or vertical).
* Soft tissue augmentation less than 2 months before implant placement

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-03-2017
Enrollment:	17
Type:	Anticipated

Medical products/devices used

Generic name:	On1 concept NobelActive implant
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	07-04-2017
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	26648
CCMO	NL60896.072.17